The Expanding Role of the Global Harmonization Task Force

Larry Kessler, Sc.D, Director, Office of Surveillance and Biometrics, CDRH, FDA

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Mutual Recognition vs. Global Harmonization

- Mutual recognition based on principle that each Competent Authority will provide market access by recognizing ability of the foreign entity to conduct appropriate activities, e.g., inspections, vigilance
- Harmonization attempts to adjust regulations toward equivalence status, providing benefit for regulators and industry by elimination of duplicative processes

Global Harmonization Task Force

- An international consortium
- Includes regulatory bodies and industry representation from North America, Europe, Japan, and Australia
- Mission: Harmonize medical device regulations for participating countries and provide a model for world regulation
- Bulk of effort conducted via Study Groups

GHTF Study Groups

- SG1: Premarket Review/Technical Requirements
- SG2: Medical Device Vigilance and Postmarket Surveillance
- SG3: Quality System Requirements and Guidance
- SG4: Auditing

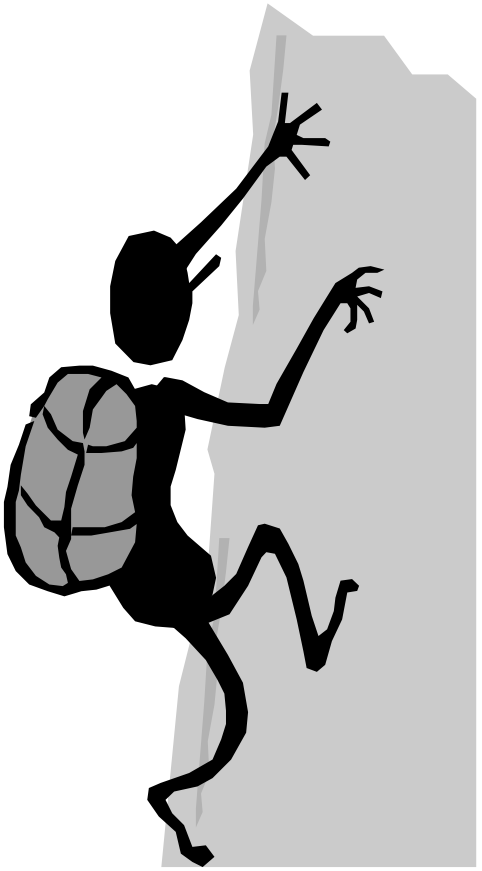
An Example of Challenges Facing GHTF Comparison of Conceptual Frameworks US vs. EU

- **Low Risk:**
  - **Substantial equivalence; self certification**
- **Medium risk:**
  - **Substantial equivalence; special controls; premarket review**
- **High risk:**
  - **Safety and effectiveness; premarket review**

- **Low risk:**
  - **Essential requirements; self certification**
- **Medium risk:**
  - **Essential requirements; 3rd-party review or corporate review**
- **High risk:**
  - **Safety and performance data; 3rd-party premarket review**

SG1 Efforts: Challenges

- GHTF.SG1.N020R1 - "Essential Principles of Safety and Performance of Medical Devices." Represents a worldwide baseline for medical device requirements. Available for public comment.



SG1 Efforts: Next Steps

- Working on Summary Technical File document (to demonstrate safety and performance or meet essential principles for Competent Authorities, Notified Bodies)
- General guidelines for device classification (suggesting a risk-based approach)
- Harmonizing use of standards in premarket review/evaluation

GHTF: Study Group 2

Mission: The purpose of a vigilance and postmarket surveillance system is to improve the protection of the health and safety of patients, users, and others by reducing the likelihood of similar adverse incidents being repeated in different places at different times.

GHTF SG2: Basic Approach

- Initial focus: vigilance/AE reporting from manufacturer reporting to NCA
  - Regulatory comparisons
  - Minimum data set
  - Vigilance case definition/ and NCA to NCA reporting
  - Standardized rules for reporting

GHTF SG3: Making Progress

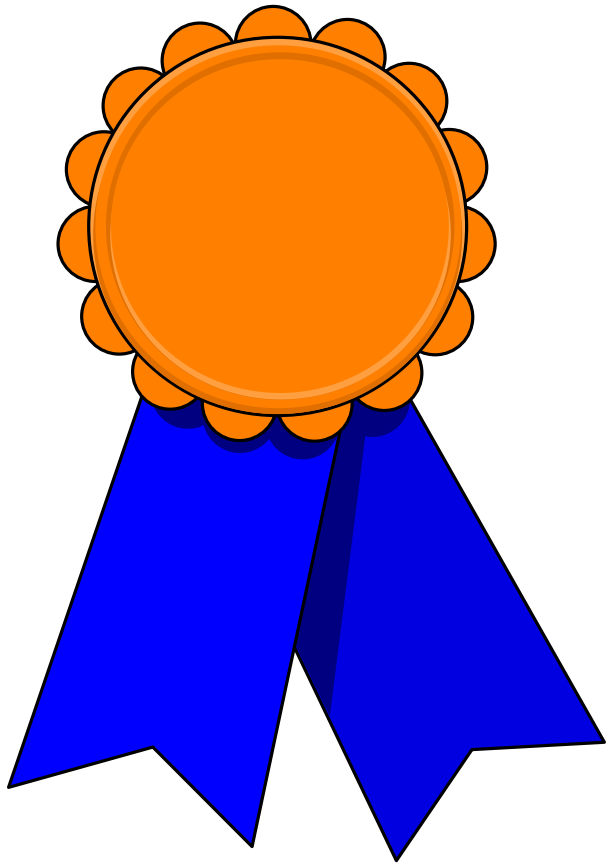
- Design controls: ***in implementation phase***
- Process Validation: draft out for comment summer 1998; final expected June 1999
- Quality Planning: next on the horizon, an opportunity for input

GHTF SG4: Harmonizing Auditing

- **Guidance developed**
  - **General Requirements (completed)**
  - **Language of audit (comments under review)**
  - **Audit duration (issued for comment)**
- **Under Development: Auditor training; Audit Report; Procedures for an observed audit; Audit strategy**

GHTF: Accomplishments

- SG2: Agreement on reporting principles
- SG3: EU requirements for quality systems and FDA-GMPs: **Harmonized!**
- SG4: Joint audits by multiple countries: draft of auditing practice guideline



Formalizing GHTF Procedures

- Meeting held of the key regulatory bodies (U.S., E.U., Japan, Canada, Australia) to move toward formalization
- Draft of procedures circulated
- To be presented for approval by consensus of the GHTF Plenary at June meeting in Bethesda, MD

Chairmanship and Next Meeting

- Dr. Elizabeth Jacobson, Acting Director CDRH/FDA to Chair GHTF for 1998-99
- Next meeting in Washington, D.C. area: June 27-July1, 1999
- Elizabeth Pieterson, Acting Director, Medical Devices Bureau, TPP, Health and Welfare, Canada to chair 1999-2000

NEW GHTF WEBSITE!

- FDA has supported the development of a brand new website devoted solely to GHTF
- Website will likely travel with the chair of the GHTF
- http://www.ghtf.org

Liaison Relationship with ISO TC210

- Developing an agreement whose goals are:
  - Promote communication
  - Avoid duplication
  - Provide a formal and coordinated regulatory voice to TC210
  - Promote fit of international standards
  - Utilize expertise of TC210 to improve regulatory efficiency
  - Promote knowledge of GHTF to TC210

GHTF: Future Prospects

- **Study Group recommendations: debate, adopt, move to implementation**
- **Premarket: expand use of standards, true conformance difficult; continue to build common dossier**
- **In vigilance area, "buy-in" from Competent Authorities is needed, harmonization soon**
- **In GMP/Q.S.R. and Auditing, international harmonization becoming a reality**
- **Increase use of World Wide Web and Information Technology**

Challenges for Regulators and Industry

- Understand differences in conceptual frameworks
- Continue to participate in international standards
- CHALLENGE: Pay attention to GHTF documents and pilot tests
- Gain international trust for all Study Group efforts